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10/669,576

09/24/2003

Dieter Hochrainer

1/1401

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05/07/2007

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EXAMINER

MITCHELL, TEENA KAY

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

05/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/669,576 | Applicant(s) HOCHRAINER ET AL. | |
| | Examiner Teena Mitchell | Art Unit 3771 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,9,10,12-14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,9,10,12-14,18 and 20 is/are rejected.
- 7) ☒ Claim(s) 16,17,19,21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/20/07 has been entered.

Claim Objections

Claim 21 is objected to because of the following informalities: In line 2, "...the inlet channels..." previously there has only been claimed one inlet channel and now applicant is claiming more than one (i.e., the inlet channels. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 18 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation "...the outlet section..." in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "...the outlet of the mouthpiece..." in lines 3 and 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et.al. (6,089,228).

Smith in a dry powder inhaler discloses a mouthpiece (32) for dispensing pharmaceutical drug formulations, a Laval nozzle communicating with the mouthpiece (at 14 and where the nozzle narrows (note illustration of Fig. 12B below), a device for supplying a powder formulation in communication with the Laval nozzle (342), an auxiliary energy source in the form of a pressure medium system (338, 390) in communication with the device for supplying the powder formulation, upon activation of the pressure medium system a gaseous pressure medium is released into the device for supplying the powder formulation and forms an aerosol with the powder formulation in such a way that the powder particles are present in dispersed form within the gaseous pressure medium prior to entering the Laval nozzle entering the mouthpiece and leaving the inhaler.

Gas enters and
flows into the
powder prior to
exiting the
Laval nozzle

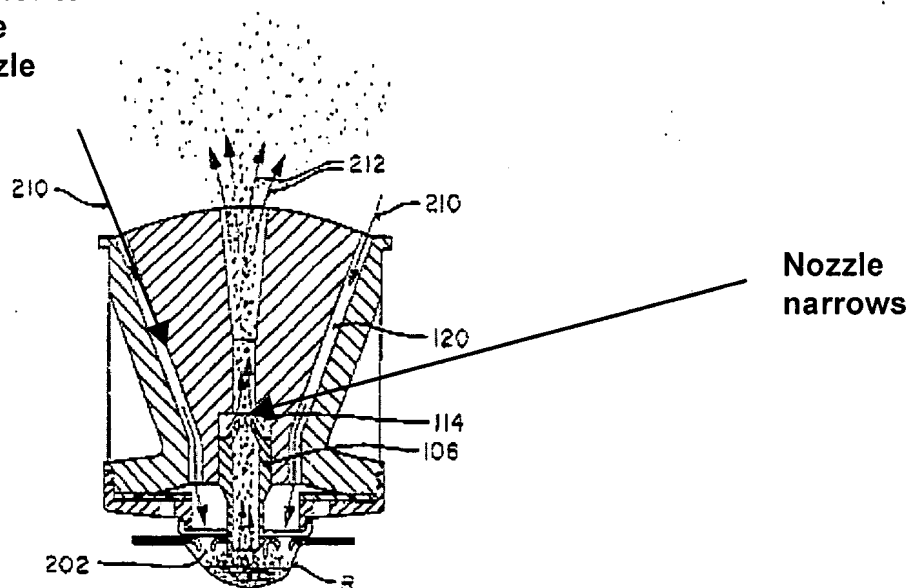


FIG. 12B

With respect to claim 7, Smith discloses that the narrowest cross section of the Laval nozzle is about 100 μm to 1500 μm (Col. 14, lines 59-67).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 13, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Taplin et.al. (2,693,805).

Taplin in a dry powder inhaler discloses a mouthpiece (M) for dispersing pharmaceutical drug formulations, having a Laval nozzle (at 21) in communication with the mouthpiece (M), a device (10) for supplying a powder formulation in communication with the Laval nozzle, an auxiliary energy source in the form of a pressure medium (17, 15, 14, 12) in communication with the device for supplying the powder formulation wherein upon activation of the pressure medium system a gaseous pressure medium is released into the device for supplying the powder formulation, and forms an aerosol with powder formulation (P) in such a that the powder particles are present in dispersed from within the gaseous pressure medium prior to entering the Laval nozzle entering the mouthpiece (M) and leaving the inhaler.

With respect to claim 9, Taplin discloses that the pressure medium system includes a pump (17) that uses ambient air as the pressure medium.

With respect to claim 13, Taplin discloses that the device for supplying the powder formulation is placed between the pressure medium system and the Laval

nozzle (at 21) in such a way that the pressure medium must pass through the device (Figs. 1-4).

With respect to claim 18, Taplin discloses an inlet channel (24), whereby inhalation air is drawn in through the inlet channel, and whereby a swirling flow of the inhalation air is created between the outlet section and the outlet of the mouthpiece (Fig. 2).

With respect to claim 20, Taplin discloses that the Laval nozzle and an inlet channel (24) for inhalation air are arranged in such a way that the aerosol flow leaving the Laval nozzle and the inhalation air collide with each other at an angle (Fig. 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 10, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et.al. (6,443,152).

Lockhart in a powder inhaler discloses a mouthpiece (because the device can be delivered via the patient's or user's nose or mouth, the device is inherently readable upon a mouthpiece as delivery of medicament to a user's mouth is known to be with a mouthpiece) for dispersing pharmaceutical drug formulations, a Laval nozzle communicating with the mouthpiece (at 48, based upon a Laval nozzle being convergent-divergent nozzle (i.e., venturi-like), the nozzle of Lockhart is readable upon a Laval nozzle), a device for supplying a powder formulation in communication with the Laval nozzle (20), an auxiliary energy source in the form of a pressure medium system (52) in communication with the device for supplying the powder formulation, wherein upon activation of the pressure medium system a gaseous pressure medium is released into the device for supplying the powder formulation (20), and forms an aerosol with the

Art Unit: 3771

powder formulation in such a way that the powder particles are present in dispersed form within the gaseous pressure medium prior to entering the Laval nozzle (Figs. 2-4, 6, 7) entering the mouthpiece and leaving the inhaler.

With respect to claim 10, Lockhart discloses that the pressure medium system includes a cartridge that stores the pressure medium (54, based upon standard dictionary definition of a cartridge, "A small modular unit of equipment designed to be inserted into a larger piece of equipment" inasmuch as 54 is inserted into 52, element 54 is readable upon a cartridge).

With respect to claim 12, Lockhart discloses the claimed invention except for the pressure medium is air, N₂, CO₂, Ar, or He. One of ordinary skill in the art at the time the invention was made would have found it obvious to use the claimed pressure medium based upon the particular medicament being used as different medications would require different pressure mediums in order to ensure the proper delivery of the medicament to the proper area of the user being treated and because certain medicaments would not disperse correct with certain pressure mediums being used. Therefore the use of the claimed specific pressure medium is deemed to be a design consideration, which would have been obvious to one of ordinary skill, note remarks above.

With respect to claim 13, Lockhart discloses that the device for supplying the powder formulation (20) is placed between the pressure medium system (52) and the Laval nozzle (48) in such a way that the pressure medium must pass through the device.

With respect to claim 14, Lockhart discloses that the device for supplying the powder formulation (20) comprises a capsule filled with powder.

Response to Arguments

Applicant's arguments filed 12/11/06 have been fully considered but they are not persuasive. Applicant argues that the with newly added limitations of "...a gaseous pressure medium is released into the device for supplying the powder formulation and forms an aerosol..." note added limitations in the rejection above. Smith is readable upon the newly added claim limitations. Applicant argues that Smith medicament reaches the throat 18 via vacuum (not by pressure as claimed) the examiner directs applicant to Fig. 12B which shows gas pressure into the powder formulation thereby causing the gas and powder to mix prior to entering the throat as applicant claims the device of Smith functions, therefore the examiner has maintained the rejection of Smith. New rejections have been made with respect to claim 1 and other claims, note rejections above. The examiner has removed the rejection of the WO 90/07351 rejection based upon the newly added limitations of claim 1.

Allowable Subject Matter

Claims 16, 17, 19, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-

Art Unit: 3771

4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Teena Mitchell
Primary Examiner
Art Unit 3771
April 28, 2007

TKM
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